# **Guidance Note on Research Ethics Committee Structure and Levels of Risk.**

## Wrexham University is dedicated to maintaining the highest standards of rigour and best practices in all research activities. Research ethics reviews assess both the likelihood and severity of potential risks, taking into account the specific ethical considerations relevant to each situation.

## **University Two-Tiered Research Ethics Review Process**

The University employs a two-tiered system for reviewing research ethics based on the potential ethical risks involved:

* **Minimal-risk research** is evaluated by a Faculty Research Ethics Committee (FREC) through a pool of reviewers. This review process is conducted remotely using the online system, eliminating the need for formal committee meetings.
* **Research involving more than minimal risk** is reviewed by the University Research Ethics Committee (UREC), which convenes monthly.

The [Wrexham Research Ethics System](https://wris.wrexham.ac.uk/main/home) includes filters that alert the central ethics team to research proposals that may pose more than minimal risk. These applications are screened by the Chair of the UREC to determine the appropriate review path.

It is essential that ethics applications are completed with honesty and transparency, fully declaring and discussing all potential risks. Importantly, minimal risk does not equate to a lowered standard for ethical review. Applications assessed as involving minimal risk may be reviewed by fewer individuals and might not require a full committee review. However, the perception of minimal risk should never be used as a justification for submitting a poor-quality research ethics application.

## **More than minimal risk**

Research that involves ‘more than minimal risk’ may include the following scenarios:

* **Vulnerable Populations**: This category encompasses children, young people, and potentially vulnerable individuals. Vulnerability can be defined in various ways; therefore, researchers should evaluate potential vulnerabilities within the specific context of their research.
* **Sensitive Topics:** Research involving potentially sensitive, embarrassing, or distressing topics may include participants’ sexual behaviour, illegal or political activities, experiences of violence, abuse, exploitation, mental health issues, or aspects of their personal or family lives, including their gender or ethnic identity.
* **Participants Lacking Decision-Making Capacity:** Researchers must be cautious when working with participants who may lack the capacity to make informed decisions or who lose that capacity during the research project. In the UK, conducting research with these individuals may require NHS ethical approval under the Mental Capacity Act 2005.
* **Identifiable Participants:** Research that generates or utilises data involving individuals who can be identified may require careful consideration. This includes data from individuals in public roles or those representing professional viewpoints (such as elite interviews).
* **Human Material and Remains:** Any research involving human biological materials or remains falls into this category.
* **Invasive Interventions:** This includes research that requires invasive procedures such as the administration of substances, surgical incisions, or other physical interventions.
* **Animal Research:** Research that involves animals must adhere to specific ethical guidelines.
* **Deception and Covert Research:** Any research that involves deception, covert observation, or is conducted without participants’ valid and informed consent raises ethical concerns.
* **Access to Sensitive Records**: Research that involves access to personal or sensitive confidential information, or working with sensitive administrative or controlled data, necessitates careful ethical scrutiny.
* **Duty to Disclose:** Topics that raise the question of whether there is a duty to disclose information shared during the research.

## **Examples of Minimal Risk Research:**

* Questionnaires of the general population that involve non-sensitive or non-distressing topics.
* Interviews or focus groups with professionals discussing their area of expertise or with the general population on non-sensitive subjects.
* Research involving non-invasive or minimally invasive activities, such as cognitive tasks, reading materials, or reviewing videos.
* Overt observational studies where participants are not considered vulnerable within the research context.

## **Applications which are automatically referred to UREC but might not be considered More than Minimal Risk**

Certain types of applications are automatically flagged for UREC approval, even if they may not present more than minimal risk. These include:

* **Research Conducted Outside the UK:** Research conducted outside the UK does not necessarily carry more risk than research conducted within the UK. However, these applications undergo screening by the central research ethics team to ensure that all relevant overseas approvals and processes are in place before being forwarded to the appropriate committee for review.
* **Recognition of External Approval:** If approval has already been granted by a recognised external research ethics committee, Wrexham University still requires its own approval. Such applications are automatically flagged for UREC review and are processed and approved via the Chair's Action.
* **Generic Applications**: Researchers can submit generic applications for projects that fall within a taught module encompassing multiple similar research projects. These applications should inherently present minimal risk; however, they are flagged for UREC approval to confirm they fit the definition of a generic application before being referred to the relevant faculty research ethics committee.
* **Professional Service Applications:** Applications submitted by Professional Service or OpTIC staff at Wrexham University are automatically flagged for UREC approval because they do not have their own minimal risk research ethics committee.
* **No Approval Required:** Applications that do not require research ethics approval

under the University Research Ethics Policy are flagged for UREC approval and processed by the central research ethics team as “No Approval Required.” These applications are not reviewed by a committee.